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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/630,307

07/30/2003

Joel M. WasDyke

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EXAMINER

BUI, VY Q

ART UNIT

PAPER NUMBER

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MAIL DATE

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12/31/2009

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/630,307	<b>Applicant(s)</b> WASDYKE, JOEL M.	
	<b>Examiner</b> Vy Q. Bui	<b>Art Unit</b> 3773	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 22 September 2009.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 13-22,24,31,33 and 34 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 13-22,24,31,33 and 34 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

**DETAILED ACTION*****Claim Rejections - 35 USC § 102/103***

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 13-17, 19-21, 24, 31, 33-34 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Kleshinski-5,776,162.

As to claims 13-17, 19-21, 24, 31, 33-34, Kleshinski-'162 (see reproduced and annotated Fig. 1 on next page; C 1, L 24-43; C 3, L 10-22; claims 1-4) discloses filter device 10 implanted in a blood vessel made of a shape memory/ nitinol/ super-elastic material having a transition temperature **about** a body temperature (98.6 F: C 1, L 39-42; claim 4) comprising:

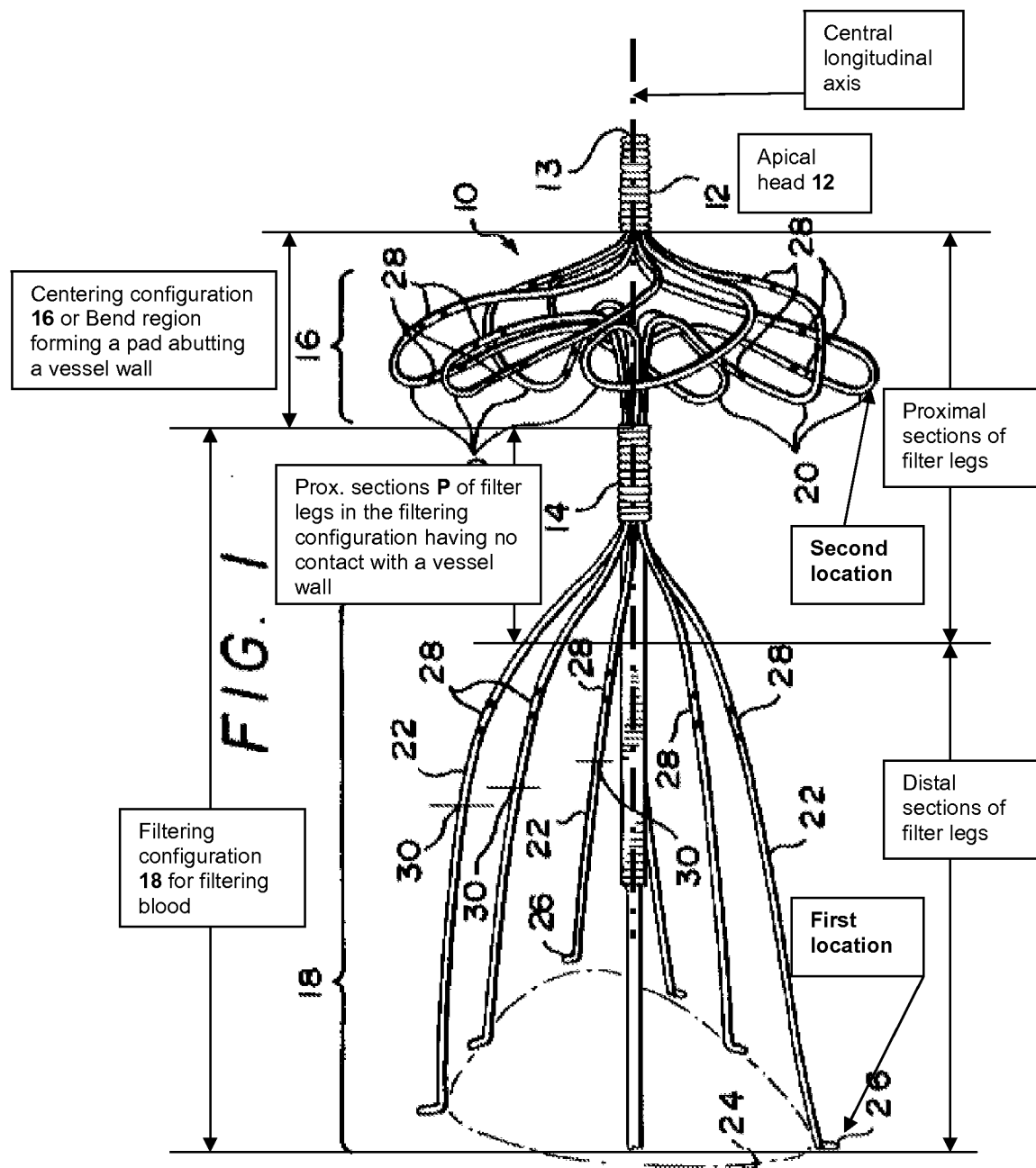
1. apical head 12 having tip 13 and a central longitudinal axis passing tip 13;
2. generally symmetrical filter basket 18 (C 3, L 27-29) in a filter configuration having filter legs 22 with means for attachment/ hooks 26 (Fig. 1) attached to a blood vessel at a 1<sup>st</sup> location for filtering a blood flow;
3. generally symmetrical filter basket 16 (C 3: L 27-44) in a centering configuration having filter legs 20 with bends to form a bend region or a pad to abut the vessel wall (Fig. 1) at a 2<sup>nd</sup> location for filtering a blood flow and for centering the filter device inside the blood vessel.

In a radially collapsed configuration, the filter device is received in a fine plastic tubing or catheter for deployment (C 3, L 10-29) and filter legs 20/22 of the device are straightened and collapsed against one another in the tubing for deployment the filter percutaneously into the blood vessel. The filter device expands inside the blood vessel when the filter is pushed out of the tubing.

Basket 16 and 18 are symmetrical about the central longitudinal axis passing through filter tip 13 (see C 3, L 27-29). Inherently, legs 20/22 are substantially disposed equidistantly

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apart from the longitudinal axis of the filter device. Alternatively, it would have been obvious to one of ordinary skill in the art to arrange legs 20/22 at equidistant interval from the central longitudinal axis to keep the filter device aligned with a lumen of a blood vessel.



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As to claims 31 and 33, Kleshinski-'162 discloses substantially the claimed invention, except for the bend region 16 including six legs arranged at equidistant 60 degree intervals. However, it would have been obvious to one of ordinary skill in the art to provide bend region 16 including a configuration of six legs arranged at equidistant 60 degree intervals as six legs would make the bend region having a lower profile in a collapsed configuration than that of seven legs to facilitate the deployment of filter device 10.

***Claim Rejections - 35 USC § 103***

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

1. Claim 18 is rejected under 35 U.S.C. 103(a) as being unpatentable over Kleshinski-5,776,162 in view of Boylan et al-6,602,272.

Kleshinski-'162 discloses substantially the claimed invention, except for the shape memory material of the device is a nickel-titanium-cobalt alloy. However, Boylan-'272 (claims 8 and 21) discloses a blood filter device comprising a Ni-Ti-Cobalt alloy. It would have been obvious to one of ordinary skill in the art at the time of the invention to make a filter as taught by Kleshinski-'162 with a Ni-Ti-Cobalt alloy as this material is well known and proper for making a blood filter device as taught by Boylan et al-6,602,272.

2. Claim 22 is rejected under 35 U.S.C. 103(a) as being unpatentable over Kleshinski-5,776,162 as applied to claim 13 above in view of Mazzocchi et al.-6,949,103.

Kleshinski-'162 discloses substantially the claimed invention, except for the lubricious coating of the device. However, Mazzocchi-'103 (col. 12, lines 7-22) discloses that it is well

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known to have a lubricious coating to control thrombogenicity of a blood filter. It would have been obvious to one of ordinary skill in the art at the time of the invention to provide a lubricious coating for the Simon-'908 blood filter device as recited in the claims for this configuration is well known in the art for controlling the thrombogenicity of the blood filter device.

### ***Response to Arguments***

Applicant's arguments filed 12/09/2009 have been fully considered but they are not persuasive.

1. Applicant (Remarks, page 5/8, paper 12/09/2009) argued that "Kleshinski does not appear to teach a plurality of filter legs actuatable between three distinct configurations, as required by the pending claims".

However, it is clearly that the collapsed configuration, the filtering configuration and the centering configuration are distinct configurations because they have distinct shapes and functions. From a collapsed configuration, filter device 10 of Kleshinski is pushed out distally from a tubing/catheter, filter legs portion 22 will be first actuated into a filter configuration, then filter leg portions 20 will be actuated into a centering configuration when the filter device 10 of Kleshinski is distally pushed further.

2. Applicant (Remarks, page 6/8, paper 12/09/2009) argued that "Applicant notes that in rejecting the claims, the Examiner has failed to address the limitation of claims 35-36. This is taken as an express admission that the limitation of the claims is not taught or suggested by Kleshinski. Thus, without conceding the correctness of the present rejection(s), Applicant has added this limitation to claims 13 and 24 in the interest of advancing prosecution. The limitation

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requires that the proximal section of each leg avoid contact with the vessel wall when the legs are in the filtering configuration”.

However, a proximal section of each leg 20/22 clearly show section configured to avoid contact with the vessel wall, for example, please see proximal section **P** of the filter configuration in the above reproduced and annotated F 1.

3. Applicant (Remarks, page 6/8, paper 12/09/2009) argued that “Applicant also notes that the first filter basket 16 of Kleshinski is "made up a series of seven overlapping loops 20 arranged to form a rosette" [sic] (column 3, lines 32-33). Seven loops cannot be equidistantly spaced at 60-degree intervals as asserted in the Office Action (page 2, last paragraph)”.

However, it would have been obvious to one of ordinary skill in the art to modify the Kleshinski filter device to have six legs arranged as claimed as indicated in the above rejection.

4. Applicant (Remarks, page 6/8, paper 12/09/2009) argued that " Additionally, the bend region of loops 20 forming a pad appear to curve circumferentially (as most easily seen in Figure 1 where loop 20 crosses over the wires as they enter the proximal end of coil 14) and do not appear to extend radially outward at equidistant intervals, as claimed.”.

However, loops 20 extend radially outward from a location near apical head 12 or near the central longitudinal axis, and return back to a location near coil 14 or near the central longitudinal axis. As indicated above, Kleshinski discloses basket 16 is symmetrical, therefore the loops 20 must radially extend equidistantly from the central longitudinal axis as recited in the claims.

***Conclusion***

**The claims have not been amended to clearly define the present invention over the prior art of reference as indicated in the above rejection.**

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Vy Q. Bui whose telephone number is 571-272-4692. The examiner can normally be reached on Monday-Tuesday and Thursday-Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jackie Ho can be reached on 571-272-4696. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Vy Q. Bui/

Primary Examiner, Art Unit 3773